IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9369

Bartle, J. November 4, 2014

Martha M. Brown ("Ms. Brown" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In November, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Jack L. Schwade, M.D., F.A.C.P., F.A.C.C. Dr. Schwade is no stranger to this litigation. According to the Trust, he has signed at least 174 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated October 4, 2002, Dr. Schwade attested in Part II of Ms. Brown's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to

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2. (...continued)
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

60%.[3] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $501,985.[4]

In the report of claimant's echocardiogram, Dr. Schwade stated that Ms. Brown had "moderate mitral regurgitation," which he measured at 26%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In February, 2004, the Trust forwarded the claim for review by Waleed N. Irani, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Irani concluded that there was no reasonable medical basis for Dr. Schwade's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. In support of his determination, Dr. Irani explained: "[mitral regurgitation] mild

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3. Dr. Schwade also attested that claimant suffered from moderate aortic regurgitation and New York Heart Association Functional Class I symptoms. These conditions are not at issue in this claim.

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's findings of a reduced ejection fraction and an abnormal left atrial dimension, each of which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

with RJA overtraced and LAA measured in off axis foreshortened view."

Based on Dr. Irani's finding that claimant had only mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Brown's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[5] In contest, claimant argued that there was a reasonable medical basis for Dr. Schwade's Green Form representation as to moderate mitral regurgitation. In support, claimant submitted a declaration from Dr. Schwade wherein he stated that he disagreed with Dr. Irani that there was no reasonable medical basis for the Green Form representation that claimant has moderate mitral regurgitation.[6] Claimant further contended that the concept of inter-reader variability, which she claimed can be as much as 26% for mitral regurgitation, accounted for the differences in opinions between the attesting physician and the auditing cardiologist.[7] Finally,

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5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Brown's claim.

6. Dr. Schwade also attached two still frame images from claimant's echocardiogram, which purportedly demonstrated moderate mitral regurgitation.

7. In support of this argument, claimant submitted a partial

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claimant argued that: (1) the auditing cardiologist's opinion was inadmissible ipse dixit[8] because Dr. Irani failed to explain the basis for his opinion that there was no reasonable medical basis for the attesting physician's Green Form representation that claimant suffered from moderate mitral regurgitation; (2) the auditing cardiologist did not provide any measurement or estimation of the quantity of claimant's mitral valve regurgitation; and (3) the audit system was flawed because the auditing cardiologists ignored inter-reader variability and also deprived claimants of their due process rights.[9]

The Trust then issued a final post-audit determination, again denying Ms. Brown's claim. Claimant disputed this final determination and requested that the claim proceed to the show

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7. (...continued)
transcript of testimony from John Dent, M.D., the Trust's expert during the September, 2002 hearings that ultimately resulted in the court's issuance of PTO No. 2640 (Nov. 14, 2002), and an article concerning inter-reader variability published by the American College of Cardiology.

8. Ipse dixit is Latin for "he himself said it." It stands for the proposition that something is asserted but not proved. Black's Law Dictionary 847 (8th ed. 2004).

9. Claimant also submitted a report of Khatab M. Hassanein, Ph.D., and Ruth S. Hassanein, Ph.D. In their report, the authors opined, based on a number of statistical manipulations, that law firms and physicians did not engage in a scheme to commit fraud and that the audit system is unreliable. Claimant did not attempt to explain how these findings had any impact on Dr. Irani's review of her specific claim. As we consistently have stated, the relevant inquiry is whether a claimant has established a reasonable medical basis for his or her claim, an inquiry that is to be made on a case-by-case basis. See, e.g., Mem. in Supp. of PTO No. 6280 at 9 (May 19, 2006).

cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5242 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on October 4, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[10] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

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10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's representation that Ms. Brown suffered from moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Brown reasserts the arguments she made in contest. In addition, although claimant continues to argue that inter-reader variability can account for a difference of 26%, she also contends that "'Reasonable Medical Basis' includes the possibility of up to 10% variation between board certified cardiologists of the same level of certification." Finally, claimant also argues that Dr. Irani did not adequately respond to the two still frame images submitted by the attesting physician and did not follow the Audit Rules.

In response, the Trust argues that Dr. Schwade's declaration does not establish a reasonable medical basis for the finding of moderate mitral regurgitation as he did not address the findings of Dr. Irani at audit. The Trust also submits that:

(1) the auditing cardiologist properly conducted the audit of Ms. Brown's claim and was not required to provide measurements as to the level of claimant's mitral regurgitation; (2) inter-reader variability does not account for the difference in the opinions of Dr. Schwade and Dr. Irani; and (3) claimant was afforded due process in these proceedings.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. In particular, Dr. Vigilante stated, in relevant part:

> Visually, trace mitral regurgitation was suggested in the parasternal long-axis view and mild mitral regurgitation was suggested in the apical views. I digitized those cardiac cycles in the apical views in which the mitral regurgitant jet was best evaluated. I then digitally traced and calculated the RJA and LAA. I was able to accurately planimeter the RJA in the mid portion of systole. In the apical four chamber view, a small mitral regurgitant jet was seen traveling immediately above the mitral annulus. This did not reach the back of the left atrium. The largest representative RJA in the apical four chamber view was 1.6 cm2. The LAA in the apical four chamber view was 20.3 cm2. Therefore, the largest representative RJA/LAA ratio was 8%. This ratio did not come close to approaching 20%. The RJA was less than 1.0 cm2 in the apical two chamber view and the RJA/LAA ratio in the apical two chamber view was less than 8%. The sonographer had one RJA determination of 3.42 cm2 in the apical four chamber view and an LAA determination of 13.3 cm2 in the apical four chamber view. There were no sonographer determinations in the apical two chamber view. The sonographer's supposed RJA was inaccurate as

> it included a great deal of low velocity and non-mitral regurgitant flow. In addition, the sonographer's LAA determination was inaccurately small as the left atrium was planimetered in an off-axis view in the apical four chamber view. An LAA determination of 13.3 cm2 would be inconsistent with left atrial enlargement. The two screen shots submitted by Dr. Schwade are the same images evaluated by the sonographer. Dr. Schwade's RJA determination of 3.75 cm2 is inaccurate as it contained a great deal of low velocity and non-mitral regurgitant flow. Dr. Schwade's LAA determination of 13.13 cm2 also was inaccurate as this was the same off-axis view of the left atrium used by the sonographer and in the inaccurate determination of the LAA of 13.3 cm2.
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> [T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a. That is, the echocardiogram of October 5, 2002 demonstrated mild mitral regurgitation with comments as above. The RJA/LAA ratio did not come close to approaching 20%. An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability.[11]

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. As an initial matter, we disagree with Ms. Brown that Dr. Schwade's supplemental declaration and still frame images provide a reasonable medical basis for his Green Form representation that claimant had

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11. Dr. Vigilante noted that claimant's echocardiogram of attestation was dated October 5, 2002, not October 4, 2002, as represented in the Green Form and on the echocardiogram report. The parties do not dispute that the echocardiogram report dated October 4, 2002 is the report of claimant's October 5, 2002 echocardiogram.

moderate mitral regurgitation. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See Mem. in Supp. of PTO No. 2640 at 9-13, 15, 21-22, 26.

Dr. Irani reviewed claimant's echocardiogram and concluded that the level of claimant's mitral regurgitation was incorrectly determined to be moderate as a result of inaccurate measurements, namely, the RJA was overtraced and the LAA was measured in an off-axis view.[12] The Technical Advisor, Dr. Vigilante, also determined that the conclusion of moderate mitral regurgitation resulted from the improper inclusion of "low velocity and non-mitral regurgitant flow" as well as a measurement in an "off-axis view." In addition, Dr. Vigilante reviewed the two still-frame images Dr. Schwade submitted and determined they contained the same improper measurements made by

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12. For this reason, we reject claimant's arguments that the conclusions of Dr. Irani constitute ipse dixit or mere disagreement with the attesting physician.

the sonographer on the echocardiogram. Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.

Further, claimant's reliance on inter-reader variability to establish a reasonable medical basis is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. Here, the auditing cardiologist and Technical Advisor concluded that claimant's mitral regurgitation was mild.[13] Dr. Vigilante also specifically found that claimant's largest representative RJA/LAA ratio was 8% and that her RJA/LAA "did not come close to approaching 20%." Adopting Ms. Brown's argument would allow a claimant to recover Matrix Benefits when his or her level of mitral regurgitation is below the threshold established by the Settlement Agreement. This result would render meaningless the standards established in the Settlement Agreement.

We also disagree with claimant that Dr. Irani's use of visual estimation was improper. Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having mild aortic regurgitation, it does not specify that actual measurements must be made on the echocardiogram. As

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13. Dr. Vigilante specifically determined that an echocardiographer could not reasonably conclude that claimant had moderate mitral regurgitation "even taking into account inter-reader variability."

we have explained, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." See Mem. in Supp. of PTO No. 2640 at 15. Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a revision and claimant's argument is contrary to the "eyeballing" standards we previously evaluated and accepted in PTO No. 2640.[14]

Finally, claimant's argument that the Trust deprived her of due process is without merit. It is claimant's burden in the show cause process to show why she is entitled to Matrix Benefits. See Audit Rule 24. The Audit Rules, as approved by this court, comply with due process requirements as claimant has had notice and an opportunity to present her evidence in support of her claim.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Brown's claim for Matrix Benefits.

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14. Claimant's argument fails, in any event, because the Technical Advisor, although not required to, measured the level of Ms. Brown's mitral regurgitation, which further establishes that claimant is not entitled to Matrix Benefits.